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P.O. Box 2370 Reston, Virginia 22090 Telephone 703-620-4646

House Committee Allocates NCI $1.347 Billion, $189 Million Over President's Request For 1987

The House Appropriations Committee last week approved a budget of $1.347 billion for NCI in the 1987 fiscal year, an amount that would substantially improve the state of the cancer program over that offered by the President's budget but still short of that needed to fund all high priority

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In Brief

Senate Committee OKs Another Cigarette Tax Hike; NCI Seeking Cancer Control Science Head

SENATE FINANCE Committee approved another cigarette tax hike of eight cents per pack, which would bring the total to 24 cents. The tax increase, part of the Budget Reconciliation Act, was approved by an 11-8 vote. It was offered as a way to raise new revenue to help meet the Gramm-Rudman-Hollings targets in the FY 1987 budget, although the American Cancer Society and others are pushing hard for it as a health measure. It has a long way to go: the Senate and House Budget Committees still must act, and it must be voted upon by both houses and signed by the President. The House Ways & Means Committee rejected a similar proposal. . . . **NCI IS** looking for a new associate director in the Div. of Cancer Prevention & Control to head the Cancer Control Science Program. The position has been vacant since Donald Iverson left for the Univ. of Colorado in June. It is a GM-15 level job with a salary range of $52,262-68,700, and physicians may be eligible for a bonus up to $10,000 a year. Contact Ms. V. Crawford-Robinson, NCI Personnel Office, Bldg 31 Rm 3A32, Bethesda, MD 20892, phone 301-496-6862. Applications, with CVs and bibliographies due by Aug. 31. . . . **JOHN DALY**, chief of surgical oncology at the Hospital of the Univ. of Pennsylvania, has been appointed to the National Board of Medical Examiners Surgery Test Committee. . . . **ALBERT GUNN**, medical director of the M.D. Anderson Hospital Rehabilitation Center, has been elected chairman of the National Library of Medicine Board of Regents. . . . **ALBERT NEW**, who heads NCI's Laboratory of Animal Science, will retire from the Public Health Service to become executive director of the American Assn. for the Accreditation of Laboratory Animal Care, effective Oct. 1. AAALAC will move its headquarters from Illinois to Bethesda that month. New has been at NIH since 1973.

House Committee Gives NCI $1.347 Billion Plus $61 Million for AIDS

(Continued from page 1)
research. It is about $100 million less than requested in NCI's Bypass Budget, which was based in large part on estimated needs for establishing the resources and facilities required to meet the Year 2000 goals.

The committee's figure ($1,346,751,000) is an increase of $170.2 million over NCI's post Gramm-Rudman-Hollings total for the current fiscal year and $188.7 million over the amount requested by the White House for FY 1987, the year that starts next Oct. 1. The Administration's request would have funded only about 27% of approved competing grants, at a priority score payline of 160. The House committee's figure probably will lift those levels to about 30% and 165.

The committee report directs that NIH fund a minimum of 6,200 new and competing grants and that they be funded "at approximately the amounts recommended by peer review groups."

The committee approved a total appropriation for NIH of $6.153 billion, an increase of $1 billion over the President's request and $893 million over the 1986 level.

In addition to the allocation of $1.347 billion for NCI is $61 million for AIDS research. That would bring NCI's total to almost $1.4 billion. The AIDS figure is an estimate, as NCI's share of the total of $199 million awarded to NIH for AIDS programs. The committee flatly rejected the White House proposal that all AIDS resources be consolidated in the office of the assistant secretary for health.

The report also noted, "The committee is aware that a serious need for personnel resources exists in the NIH AIDS program, including research scientists, skilled nurses and technical support staff, and administrative and management personnel. Therefore, the committee is providing an additional 103 full time equivalent positions to NIH for the AIDS program."

The committee expressed concern over the entire issue of adequate staffing at NIH:

"In last year's report, the committee called attention to the fact that staffing levels at NIH have been drastically reduced in recent years, while appropriations have steadily increased.

"The funds in the 1987 bill should support at least 13,500 full time equivalent positions. The committee is especially concerned about staffing for patient care at the Clinical Center. . . many beds are not occupied because of lack of staff. The committee requests a special report by the NIH director on staffing at the Clinical Center, to be submitted no later than Jan. 1, 1987. This report should identify the number of patient beds in the center, the number of beds presently occupied, the number of beds needed to support the intramural research program, and the number of staff presently available for this purpose, compared with ideal staffing levels. The report should also discuss possible methods of improving recruitment and retention of nurses and other patient care related staff, such as contracting out, improving pay and benefits, recruitment into the PHS Commissioned Corps, and so on."

NCI's current position ceiling is 2,072, which is 158 fewer than in 1985. The White House proposed to retain that level for 1987; the committee directed that NCI be permitted to fill 2,209 positions.

Centers Funding

The committee expressed concern that NCI "has funded cancer center core grants differently depending on whether the centers are competing or noncompeting. The committee requests a report, to be submitted no later than Jan. 1, 1987, on the Institute's current policies with respect to funding of new cancer core grants, competing renewals, and noncompeting renewals."

Cancer center executives have been objecting to the NIH policy of considering core grants as something different than "research projects" in complying with congressional directives on funding close to recommended levels. In order to spread the money over more grants and keep alive some of those just over the paylines, NCI has made various cuts under recommended levels, depending on whether they are competing or noncompeting and sometimes on their priority scores. The centers, of course, would like to have the same privilege as RO1 and PO1 grantees and come under the congressional full funding mandate.

"Cancer centers supported by NCI are an important resource for the total National Cancer Program," the report said, indicating that centers representatives have been getting their message across. "Core grant support from NCI provides for program leadership, centralized research instruments, and facilities not otherwise available through traditional research grants. The

environment of the cancer centers facilitates scientific communication and is responsible for attracting productive cancer investigators."

The committee stopped short of intervening in the NCI-OMB fight over "apportionment" and "micromanagement."

"The committee has received numerous complaints to the effect that new methods for the apportionment of appropriations by the Office of Management & Budget are placing unnecessary restrictions on NIH program management and are creating excessive paperwork," the report said. "The committee requests a report from the NIH director on the subject not later than Jan. 1, 1987."

NCI executives and others at NIH would have liked something stronger from the committee, such as a "cease and desist" order to OMB.

The Senate Labor-HHS-Education Appropriations Subcommittee may mark up its bill next week. It probably will not go to the full committee until after the August recess. It is possible that both houses could act on the bills in September, with the conference committee turning out the final measure before the start of the fiscal year. That probably is not going to happen, which will require interim funding through a continuing resolution, until the final bill is passed.

Hughes Institute Considering More Money For Genome Mapping

Officials from the Howard Hughes Medical Institute plan to ask the organization's board of trustees for increased funding to aid in international efforts to map and ultimately sequence the human genome, HHMI President Donald Fredrickson told an informational forum held at NIH last week.

"For the last year we've been trying to understand for ourselves what might be a proper role or additional role for Howard Hughes Medical Institute," he said. Discussing the upcoming board meeting, he said, "I know for sure of one thing, that we're going to tell them that we're going to increase our efforts in the aspect of genetics. I think that phase one is worth pushing hard for, we have a very big investment in parts of phase one, and we're going to commit ourselves to that kind of activity to the extent that we can and that is proper.

"I'm also going to tell them that I think that Hughes might be able to participate in a helpful way, in a benign way, with the problem of coordination...coordination to get cooperation from scientists and also to help push for public support...it's clear that the international aspect needs to be considered and supported. One would look at the existing human gene workshop as a possible structure upon which changes might be made and might take place."

While a number of participants at the meeting questioned the value of sequencing the entire human genome, all agreed that the first phase of such an effort, a physical map, could provide important information and should be embarked upon at once.

"It's been a total red herring in my mind to emphasize the total genomic sequence as the [primary] goal," forum chairman Walter Bodmer said in a summary of the meeting's discussions. Noting that the effort can begin by making a physical map of the human genome and placing RFLPs within the map, he suggested that investigators can then look at the best sequences. "We've got an obvious starting point." The Imperial Cancer Research Fund Laboratory official also noted that "in the meantime, a lot of people are going to be doing sequences anyway."

He pointed out that the lack of consensus among scientists "is over the value of these applications."

Noting that "there's an awful lot of work going on anyway in this area," Bodmer said, "the first challenge is to take advantage of that in terms of coordinating efforts and if we get our act together in doing that, I think the question of the other aspects of it will fall into place." Bodmer also downplayed concerns by scientists that the money required for such an effort would drain resources available for traditional investigator initiated research support. "There's already a large amount of money going into" activities related to human genome mapping, he said, predicting that extra money will become available. "Concerns about the extra support money being taken away from [research programs] are all due to a misunderstanding of what is being aimed at." Bodmer told the participants that they have an "important PR job to do--first in the scientific community," then among the public at large. "I feel that the big challenge is how we can get the scientific community together for achieving these goals," he said. "I think there are a large number of aspects of this work that are supportable under the general goals. I think

it is important to emphasize that sequencing will provide valuable information about all unknowns about functions and processes."

A number of participants appeared to agree with the observation by Sydney Brenner, Medical Research Council, that "perhaps only four percent of the human genome is worth sequencing."

Japanese researcher Nobuyoshi Shimizu reported that investigators there "would prefer a physical map of a particular chromosome, and then go on to the sequencing of more important, more interesting genes.

"There is a considerable interest in human gene mapping in Japan, but there is not enough enthusiasm to go forward with general sequencing." There are currently no plans for the Japanese to proceed with sequencing the human genome, he said. Japanese officials have expressed their interest in international collaboration, but no decision has been made.

Japanese researchers have been working to develop an automated sequencer in collaboration with three major Japanese firms, Seiko, Fuji and Hitachi.

Interest in mapping the genome, but a lack of enthusiasm for sequencing was also expressed by John Tooze, executive secretary of the European Molecular Biology Organization. Tooze reported that EMBO members felt that from 95 to 97 percent of the human genome sequencing "won't be especially interesting." Tooze emphasized the importance of presenting the project "as a stepwise program."

Bodmer agreed, saying, "I think that we shouldn't emphasize at this stage the total sequencing so much as the organized map, knowing where all the functional genes are, knowing the sequences of those functional genes and understanding how they work...The ultimate endpoint could be the total sequence."

Dutch researcher Peter Pearson also expressed interest in his country's being involved in the project, "as long as it's phased in in a reasonable fashion." Representatives from a number of other nations expressed interest in participating in the project as well.

Canadian researcher Charles Scriver brought up the issue of how the information will be used to interpret for persons at risk of genetic diseases. He anticipates the need for work stations for genetic networks allowing for both input and output.

Estimates for the cost of the actual sequencing of the human genome vary widely, with the cost being largely dependent on technological advances in automated sequencing. The Japanese research into an automated gene sequencer, for example, could be expected to reduce costs and time required dramatically.

Department of Energy official David Smith told the meeting that the project "is not going to cost anything like the billions of dollars we've read about." Instead, Smith predicted that the project would cost tens of millions. An initial estimate made in March projected that 30,000 person years would be required with existing technology.

Technological advances discussed at the meeting, however, would make the project more likely to require 300 person years, he said.

DOE's expertise in computing, physics and engineering can complement efforts to mapping and sequencing, he said. DOE has completed small insert libraries at Los Alamos and is beginning cosmid libraries. Discussing the conclusions of a DOE sponsored meeting held in Santa Fe, Smith said the department intends to stimulate the development of a physical map of the human genome. The effort would start out on a relatively small scale, and would probably involve two approaches to complete the overlapping cosmid map, which would then be placed into a repository that would be made available to investigators throughout the world.

Smith and other participants stressed the need for national and international cooperation and coordination.

Other concerns raised at the meeting included the need for a unified language and standard nomenclature, and improved information handling and storage.

Discussing NIH's interest in genetic research, National Institute of General Medical Sciences Director Ruth Kirschstein noted the existence of NIH's Genbank and Bionet data bases and other resources such as a chromosome library and repository for DNA probes supported by NIH.

Kirschstein heads a committee established by NIH Director James Wyngaarden to study issues associated with mapping and sequencing the human genome. That will be the subject of the October meeting of the NIH Director's Advisory Committee.

National Library of Medicine Director Donald Lindberg suggested that the effort will require increased use of computer networking. Other advances that could be useful

in the effort include parallel processing and artificial intelligence techniques.

National Science Foundation representative John Wooly told the meeting that NSF is particularly interested in structural predictions, technology transfer and new equipment development. "We have an interest in catalyzing the creation of second generation data bases for nucleic acids, for proteins, for carbohydrates and also for linking those data bases together. This should allow more rigorous and more detailed analysis of the growing sequence information." NSF is also interested in software and hardware development, and the application of computers and computational methods to biological problems.

Discussing the cost of the sequencing itself at a recent meeting of the Board of Scientific Counselors of the Div. of Cancer Biology & Diagnosis, Janos Varga told the meeting that it depends on the development of new technologies. "The current estimates are that the equipment which will be on the market at the end of this year will increase the rate of the sequencing by about a factor of ten," he said. If the rate is further increased by another order of magnitude by the addition of automation, the cost of sequencing "will decrease rather substantially." The current cost of sequencing is about $1 per base. "That means that if the cost goes below 10 cents a base, the total cost would be about $300 million," he said.

Varga said that a preliminary phase of about five years would be likely, during which time the physical map of the genome will be completed, and perhaps another set of cosmids. The phase would include the development of equipment, a network, a repository, and some type of core organization.

Most of the sequencing would take place in the second phase, with some estimates that the whole project could be completed by the year 2000.

"Most people believe that in about 30 years from now, most of the genome would be sequenced anyway," he said. The main point of the discussions is that with an international or national concerted effort "this whole thing could be done by the year 2000. This means the benefits would come 15, 20 or 30 years earlier."

One estimate for the physical mapping of the genome by five to 10 labs suggests that it would cost $10 million. Computing costs could total $100 million, and administrative costs could be about $15 million. Varga noted that he hasn't seen any estimates for the cost of networks or repositories, but suggested that "it will be a substantial investment." Estimates for total expenses for mapping and sequencing the entire human genome range from half a billion to $3 billion.

"If such a program becomes acceptable at the national level, we think it will have a substantial impact on our programs in the DCBD and eventually we will become involved in it."

Varga cited a consensus that has been reached at a number of meetings on mapping and sequencing the human genome. "It should not be done at the expense of support for investigator initiated research."

Participants in the meetings have also agreed that any information generated should be made available to investigators throughout the world.

NIH Study Section Members Likelier To Be Successful As Grant Applicants

Current and former members of NIH study sections are about twice as likely to be successful grant applicants as scientists who are not members of study sections, according to a "DRG Peer Review Trends" chartbook recently released by NIH. The report found that "both current and former study section members have dramatically higher success rates on their research grant applications than nonmembers. For example, in 1981 and 1984 current and former members were approximately twice as likely to be successful grant applicants as nonmembers."

The report advised, however, that "despite these impressive success statistics, study section members are not immune to the effects of tight budgets, increased applications and related program priorities. Their success rates have fluctuated from year to year in the same manner as other applicants."

The success rates for nonmembers in the years analyzed ranged from a high of 43% in 1975 to a low of 30% in 1981 and 1983. The success rate for current members in the same years ranged from 71% to 59% and 53%.

Approval rates for current and former members of study sections also exceeded those of nonmembers in all review sections. "Although nonmember rates differed among the review sections (ranging from 71 to 90%), current and former members received consistently high approval rates--close to 90% in allsections."

The review also found that study section members both current and former had better average priority scores than nonmembers for both new (type 1) and competing renewal (type 2 and 9) applications.

Comparing data from 1975, and 1979 through 1984, the review found that "current members averaged between 36 and 51 points better than nonmembers." Former members also received better average scores than non members with differences ranging from 41 to 64 points.

In the most recent year analyzed, 1984, priority scores for new applications averaged 200 for current members, compared to 216 for former members and 245 for nonmembers. In renewal applications in 1984, current members' priority scores averaged 176, compared to 177 among former members and 206 for non members.

NIH noted that "the criteria for membership selection on DRG [Div. of Research Grants] study sections include competence as an independent investigator. Their proficiency is evidenced by significantly better (lower) priority scores than non members."

The number of competing applications identified from current and former members ranged from highs of 295 and 311 in Biomedical and Biological Review Sections to lows of 201 and 202 in Special and Behavioral/Neurosciences Sections. As a percent of each review sections' applications, those from current or former members ranged from a low of 6.3% in Behavioral/Neurosciences sections, 9% in Biological and Biomedical sections, to a high of 13.3% in Special sections.

The report warned that the grant record of DRG study section members "is subject to several limitations." The identification of members with NIH grant support depends on the accuracy of their recorded social security or set numbers in the CMIS and IMPAC systems.

"Therefore, members grant record may be understated by an unknown amount." For example, a grant record is not available if the member is a coprincipal investigator. Data are also not available for member support from other federal, state or local government sources or from private industry. Those sources provided the majority (63%) of health R&D support in the U.S. in 1983 and 1984.

In each year of membership from 1975 to 1983, between 69% and 75% of study section members were found to be principal investigators on one or more NIH research grants from that fiscal years funds. An additional 9 to 12% had NIH research grants in the following two years and/or another type of NIH/PHS support.

It added that "a growing proportion of members had more than one research grant--26% in 1975, increasing to 30% in 1983. Of these, members with three or more research grants increased from 6 to 7%; those with two grants increased from 20 to 23%.

In addition, a number of members had other types of NIH awards, including 99 with training grants and 15 with contracts in 1983.

The report focuses primarily on the characteristics of the members who serve on the Initial Review Groups managed by DRG. The report is the second issue of a series of annual reports on NIH peer review groups, but the first to provide coverage of institute review groups and study section members as grant applicants.

NCI Study Section Members

Additional information on the characteristics of NCI study section members was provided to **The Cancer Letter** by DRG. Of 140 NCI study section members in 1986, 74.3% held the academic rank of professor, with 25% of the members having the position of department chairman, and 72.1% "other" positions. Almost half (48.5%) of NCI study section members were employed by medical schools; 14% were employed by research and other nonprofit organizations; 12% from other health professions; 9.5% by other higher educational organizations; 8% by independent hospitals; and 4.5% by profit organizations.

NCI study section members are overwhelmingly male, with men representing 79% of membership in 1986. Female representation on the study sections was 21% in 1986, a drop from a 10 year high of 26.9% in 1983. The MD degree was the highest degree held by 45% of the study section members; 41% held PhDs, 11.5% held MD/PhDs, and 2.5% held other degrees.

In 1986, 23.5% of NCI regular study sections were age 41 to 45. The 46-50 age bracket had the next highest percentage of study section members (21%), followed by 20% for those in the 51 to 55 age bracket; 13% for ages 56 through 60; 12.5% for ages 36 to 40; and 9% for those over 60 years of age. Only 1% of NCI study section members in 1986 were under the age of 36.

When the age distribution was calculated for MDs only, the average age of an MD serving on an NCI study section was 50.2 in 1986.

There were no regular study section MD members under the age of 36 in 1986, however, that number has ranged from one MD under 36 to as many as 23 in the past 10 years. The highest percentage of MD study section members were at the age intervals of 51 to 55 (25%); 46 to 50 (22%); 41 to 45 (22%); and 56 to 60 (19%).

The average age of PhD members of study sections tends to be lower than that for MD members, with the average age of a PhD serving on an NCI study section in 1986 being 45.5. Nearly one quarter (24%) of PhDs were in the 41 to 45 age bracket; 19% were 36 to 40 years old; 14% were 46 to 50; 10% were age 51 to 55, and 9% of PhD study section members were 56 to 60. While only 2% were over 60, 4% of the study section members were under 36.

More than 275 organizations have been represented in the NCI study sections in the past decade. In 1986, the single institution with the most study section members was Yale University, which had six members. Yale was followed by the Univ. of Texas System Cancer Center and Ohio State Univ., which each had five members. Four institutions had four study section members each: Johns Hopkins Univ.; Univ. of California (San Francisco); Univ. of Chicago; and the Univ. of Southern California.

Internal medicine was the primary area of expertise with the most representation on study sections, accounting for 21% of 1986 members. Oncologists accounted for 13% of study section members.

Chemists had the next largest representation on the study sections, accounting for 8% of membership. Their position was closely followed by microbiologists, who represented 7.5% of study section membership. The field of radiology accounted for 6% of membership. Other areas of expertise representing 5% or more of study section membership were: biostatistics (5%); cell biology (5.5%); and epidemiology (5.5%).

Pathology, surgery, and the category of other clinical medicine each accounted for 4.5% of study section membership.

The NIH chartbook includes sections on the workload of study sections, educational and demographic characteristics, representation of women and minorities, and institutional aspects of membership. Copies of the report may be obtained from the Statistics and Analysis Branch, DRG, NIH, Westwood Building Rm. 1A-18, Bethesda, Md. 20892, phone 301-496-7401.

CDC's New AIDS Definition System To Increase Reported Cases Only 1%

The Centers for Disease Control's new case definition system for patients with acquired immune deficiency syndrome is expected to result in only a small number of new reportable AIDS cases, the agency said in a recent issue of "Morbidity and Mortality Weekly Reports." CDC estimates that the revision in the AIDS case definition will result in the reclassification of less than 1% of AIDS cases previously reported to CDC.

Cases reported under the revised definition will be distinguishable from cases included under the old definition in order to provide a consistent basis for interpretation of trends. CDC plans to develop draft classifications for disease manifestations of HTLV-3/LAV infections other than AIDS.

The revised case definition of AIDS used for national reporting will continue to include only the more severe manifestations of HTLV-3/LAV infection. The new definition includes the presence of five diseases that will be considered indicative of AIDS if the patient has a positive serologic or virologic test for HTLV-3/LAV in the absence of the opportunistic diseases required by the former case definition:

1. Disseminated histoplasmosis (not confined to lungs or lymph nodes), diagnosed by culture, histology, or antigen detection.

2. Isosporiasis, causing chronic diarrhea (over one month), diagnosed by histology or stool microscopy.

3. Bronchial or pulmonary candidiasis, diagnosed by microscopy or by presence of characteristic white plaques grossly on the bronchial mucosa (not by culture alone).

4. Non-Hodgkin's lymphoma of high grade pathologic type (diffuse, undifferentiated) and of B cell or unknown immunologic phenotype, diagnosed by biopsy.

5. Histologically confirmed Kaposi's sarcoma in patients who are 60 years old or older when diagnosed.

In the absence of the opportunistic diseases required by the former case definition, a histologically confirmed diagnosis of chronic lymphoid interstitial pneumonitis in a child under 13 years of age will be considered indicative of AIDS unless tests for HTLV-3/LAV are negative.

Patients who have a lymphoreticular malignancy diagnosed more than three months after the diagnosis of an opportunistic

disease used as a marker for AIDS will no longer be excluded as AIDS cases.

In order to increase the specificity of the case definition, patients will be excluded as AIDS cases if they have a negative result on testing for serum antibody to HTLV-3/LAV, have no other type of HTLV-3/LAV test with a positive result, and do not have a low number of T helper lymphocytes or a low ratio of T helper to T suppressor lymphocytes. In the absence of test results, patients satisfying all other criteria in the definition will continue to be included.

CDC published a classification system for HTLV-3/LAV associated virus infections in late May. That system is primarily applicable to public health purposes, including disease reporting and surveillance, epidemiologic studies, prevention and control activities, and public health policy and planning.

The system applies only to patients diagnosed as having HTLV-3/LAV infection and includes four mutually exclusive groups.

Group 1, **acute infection**, includes patients with transient signs and symptoms that appear at the time of, or shortly after, initial infection as identified by laboratory studies. All patients in group 1 will be reclassified in another group following resolution of this acute syndrome.

Group 2, **asymptomatic HTLV-3/LAV infection**, includes patients who have no signs or symptoms of HTLV-3/LAV infection. Patients in this category may be subclassified based on whether hematologic and/or immunologic laboratory studies have been done and whether results are abnormal in a manner consistent with the effects of HTLV-3/LAV infection.

Group 3, **persistent generalized lymphadenopathy (PGL)**, includes patients with PGL, but without findings that would lead to classification in group 4. Patients in this group may be subclassified based on the results of laboratory studies in the same manner as patients in group 2.

Group 4, **other HTLV-3/LAV disease**, includes patients with clinical symptoms and signs of infection other than or in addition to lymphadenopathy. Patients are assigned to one or more subgroups based on clinical findings: A. constitutional disease; B. neurologic disease; C. secondary infectious diseases; D. secondary cancers; and E. other conditions resulting from HTLV-3/LAV infection. There is no a priori hierarchy of severity among subgroups A through E, and the subgroups are not mutually exclusive. Patients whose clinical presentations fulfill the surveillance definition of AIDS are classified in this group.

RFPs Available

Requests for proposals described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs, citing the RFP number, to the individual named, the Blair building room number shown, National Cancer Institute, NIH, Bethesda MD 20892. Proposals may be hand delivered to the Blair building, 8300 Colesville Rd., Silver Spring MD, but the U.S. Postal Service will not deliver there. RFP announcements from other agencies will include the complete mailing address at the end of each.

RFP NCI-CM-67880
Title: Analysis of chemicals and pharmaceutical formulations for anticancer agents

Multiple cost reimbursement contracts are expected to be awarded to contractors with the capability to evaluate bulk chemicals and formulated drug products for identity, purity and drug content. Reports of the analytical testing on bulk drugs and dosage forms will be used as a basis for assessing the suitability of bulk drugs or finished dosage forms for use in screening, pharmacology studies, toxicological studies, formulation studies, or for clinical trials. These data will also be supplied to the Food & Drug Administration as part of the NCI/IND filings for new anticancer agents.

Historical summaries of the data will be used in preparing specifications for the various bulk pharmaceutical substances. These specifications will be used in procurement actions, as well as for the routine quality control of these materials.

In addition, solubility data will be developed, and selected assay methods will be adapted for the quantitation of drug in plasma. These data will be provided to other contract projects to facilitate formulation development, and to aid in the analytical aspects of pharmacology and toxicological testing.

The principal investigator should be trained in chemistry (analytical, pharmaceutical, organic, etc.), preferably at the PhD level from an accredited school, and must be thoroughly familiar with the analysis and evaluation of bulk pharmaceutical substances and clinical dosage forms. In lieu of the PhD, equivalent experience may be acceptable.

The contract period is to be five years beginning approximately June 1, 1987. The incumbent contractors are Midwest Research Institute, Research Triangle Institute, and SRI International.

Contract Specialist: Elizabeth Moore
RCB Blair Bldg Rm 216
301-427-8737

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